

**REMARKS**

In this Amendment D, claims 1, 5, and 11 have been amended to more particularly claim certain embodiments. Specifically, claims 1, 5, and 11 have been amended to indicate that the wet mixture is discharged from the discharge end without explosive decompression. Support for these amendments may be found, for example, in paragraph [0028] and in paragraph [0034] of Applicants' specification as filed.

Accordingly, upon entry of this Amendment D, claims 1-3, 5-14, and 16-22 remain pending in this application.

**Rejections under 35 U.S.C. §103(a)**

Applicants respectfully request reconsideration and withdrawal of the rejection of claims 1-3, 5-14, and 16-22 under 35 U.S.C. §103(a) over U.S. Patent No. 5,549,757 to Morano (Morano).

**1. The Claimed Subject Matter**

The present application is directed to a process that produces a dry granular sugar ingredient from sucrose and corn syrup which is suitable for production of compressed, tableted confection products by enabling them to be formed with a higher initial strength without addition of binders. As a result, the resulting compressed, tableted confection exhibits improved handling and packaging, with fewer broken and chipped tablets. (See, e.g., paragraphs [0001] and [0024].) In particular, Applicants have found that a controlled particle size distribution enables compressed, tableted confections to be produced more efficiently, more reliably, and in a more reproducible way. (See, e.g., paragraph [0036])

In Applicants' claimed process, a free-flowing granular sucrose and a corn syrup solution is fed into a twin-screw mixer and then discharged as a wet mixer to a comminutor, drying the wet mixture, sieving the dried mixture, and recovering granules of sucrose bound with corn syrup solids. An aspect of Applicants' invention is that the

solids discharged from the twin-screw mixer do not form friable or porous structures which would produce granules unsuitable for the purpose of tablet compression. The fact that there is no explosive decompression of product leaving an extruder/mixer is illustrated in Figure 1 and the description at Par. 0028, which indicates that a moist mixture discharged from mixer 20 is "dropped" onto conveyer 22. Further, the product dropped onto conveyer 22 is then sieved to break up lumps, which is not consistent with a product discharged "explosively" from an extruder/mixer.

Applicants have submitted herewith a Declaration of Joseph W. Bell, which explains that a product formed using the process of Morano is not acceptable to form a compressed product without binders.

## 2. Morano

Morano discloses processes for recrystallizing sugar that include mixing powdered sugar and an adjuvant such as invert sugar or molasses. Morano discloses that the final product form is created by his process. The mixed mass is fed into an extruder where it is "brought to a temperature and pressure such that, upon discharge from the exit die head, an "explosive decompression" occurs (e.g., col. 9, lines 29-34). The decompression, subsequently, causes the desired spontaneous recrystallization and rapid dehydration of the extruded sugar product (column 9, line 7 to 12.). Morano also discloses that extruded mixed mass undergoes an "explosive decompression as it exits the die head into the atmosphere" (col. 10, lines 41-42). "Most of the water contained in the original feed sugar blend 'flashes-off' at the outlet of the die. This flash-off of water results in the simultaneous expansion of the expelled product strands" (column 10, lines 42-45). "It is common for the expelled product strands to double in volume due to the effect of water vaporization" (col. 10, lines 49-50).

Morano specifically discloses that the "final sugar product is a porous, agglomerated structure of extremely small crystals" (column 11, lines 3-4). Morano also describes the final product as a "friable solid of open or porous structure" (column 11, lines 22-23).

Accordingly, Morano is focused on the use of extruder temperature and shear conditions which, with the use of a die plate on the discharge end of the extruder, will create an "explosive decompression" of the extruded sugar mass. The purpose of the "explosive decompression" is disclosed to be the creation of a quick expansion of the sugar mass, aiding in dehydrating the mass and creating a porous and friable structure.

Although Morano is focused on the use of the disclosed process to prepare sugar fondant (Examples 1-9 and 16), Morano does describe final products other than sugar fondant. Specifically, Morano discloses in Examples 11, 12, and 16, an excipient final material, capable of being used in pressed tablets. However Examples 11 and 12 require binder ingredients (i.e., maltodextrin and gum Arabic). Example 16 contains fruit juice concentrate, which may function as a binding material. Applicants specifically disclose that their product may be used to prepare compressed confections "without the need for adding binders" (Par. [0019]).

As pointed out in the last Office Action, Morano's Examples 17 and 18 do describe a powdered sports drink of larger particle size. Therefore, Applicants withdraw the arguments made in the previous Amendment C regarding the particle size of the Morano product. However, this powdered sports drink described in Examples 17 and 18 contains maltodextrin, along with acids, and other ingredients. These larger-particle size product also are described as "instantly soluble" (col. 17, line 56), which is consistent with a porous and friable product formed using the Morano process. As explained in this Amendment D and the accompanying Declaration of Joseph W. Bell, such a friable, porous product is not suitable to form a hard, compressed product.

Morano specifically teaches that products formed in Examples 11, 12, 16, 17, and 18 of Morano were produced using the "same procedures and equipment as described in Example 1." Thus, Applicants submit that all products were subjected to the explosive decompression as described in Morano's specification and, thus, are porous and friable.

### 3. The Claimed Subject Matter is Not Obvious Over Morano

Applicants' disclosed process creates particles suitable for making hard compressed tablets. Applicants submit that particles produced by Morano are not suitable to produce hard, compressed tablets as explained in the attached Declaration of Joseph W. Bell.

The fact that Morano teaches use of a process with an "explosive decompression" step, which creates a "friable solid of open or porous structure" material is not surprising, as a "friable solid of open or porouse structure" would give a fine resulting sugar product when ground. This use is in fact consistent with Morano's focus on the primary end use of the finished product, which is a fondant. (See, e.g., column 3, lines 9-11, in which Morano states "[t]he invention is an improved process for manufacturing sugar products containing aggregates of fondant-size sucrose crystals.") This is very different from a hard compressed confection or tablet, such as a breath mint, which uses larger particles, with only a minimum of fine particles.

Where Morano does disclose a product formed from his process to create "directly compressible excipient", the working examples require a binding agent such as maltodextrin in the extruded sugar mixture. The goal of the Applicants' process is to create a compressible sugar material which does not require added binding material in the final sugar granule, as the hardness of the compressed tablet is created by the interparticle binding created by the corn syrup of the final sugar granules. Other materials could interfere with that binding property.

Accordingly, Applicants respectfully submit there is not demonstrated motivation to modify the disclosure of Morano to arrive at Applicants' claimed subject matter. In fact, Applicants submit Morano actually teaches away from the claimed subject matter, because (1) Morano teaches using a process to create friable, porous particles; (2) Morano focuses on preparation of a fondant (from the fine particulate material) or instantly soluble sports drinks mixes (from the porous larger particles), which are distinctly different from a compressed confection (needing larger, dense particles); and

(3) Morano must add additional binder materials to its sugar mixture in order to create a compressible excipient sugar material.

In fact, Applicants respectfully submit that one of ordinary skill in the art would recognize that a particulate sugar material made with only sugar and corn syrup in accordance with Morano's process would be friable and porous and would be unsuitable for use in the preparation of a compressed confection, because such particles would not be compressible, or would result in a soft compressed confection.

As set forth in M.P.E.P. §2143, in order for the Office to establish a *prima facie* case of obviousness, three basic criteria must be met: (1) the prior art references, when combined, must disclose each and every element of the claim; (2) there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to combine or modify the references; and (3) there must be some reasonable expectation of success. Further, an obviousness determination is not the result of a rigid formula disassociated from the consideration of the facts of the case. The common sense of those skilled in the art can demonstrate why some modifications and/or combinations would have been obvious where others would not. Finally, as noted in the Examination Guidelines For Determining Obviousness Under 35 U.S.C. §103(a) in view of the Supreme Court decision in *KSR Int'l Co. v. Teleflex, Inc., et al.*, the Office must provide a reasonable explanation to support any obviousness rejection.

Applicants respectfully submit the Office has failed to establish a *prima facie* case of obviousness for a number of reasons. First, each and every element of the claims has not been disclosed or suggested by the cited reference. Additionally, or alternatively, Applicants respectfully submit the Office has failed to establish a *prima facie* case of obviousness because there is simply no motivation to modify the cited reference as suggested by the Office.

Applicants further submit that Applicants have demonstrated that Morano teaches away from Applicants' claimed invention and, therefore, Applicants have overcome any assertion of *prima facie* obviousness.

In view of the foregoing, Applicants respectfully submit motivation is clearly lacking to modify the disclosure of Morano, as suggested by the Office, in order to arrive at the claimed subject matter. Applicants further submit, again in view of the foregoing, that the Office has failed to provide a reasonable explanation to support the position that such motivation is present. Reconsideration and the withdrawal of the rejection of independent claims 1, 5 and 11 is therefore requested.

Inasmuch as all of the remaining claims depend directly or indirectly from one of claims 1, 5 or 11, these dependent claims are submitted as patentable over Morano for at least the reasons set forth above for the claim from which they depend. Accordingly, reconsideration of the rejection of these claims is also respectfully requested.

### **CONCLUSION**

In view of the foregoing, Applicants respectfully request reconsideration of the rejection of claims 1-3, 5-14, and 16-22 and allowance of all pending claims.

Applicants do not believe any fees are due in connection with this Amendment D; however, the Commissioner is hereby authorized to charge any fees which may be required to Deposit Account No. 01-2384 in the name of ARMSTRONG TEASDALE LLP.

Respectfully submitted,

/Derick E. Allen/

Derick E. Allen, Reg. No. 43,468  
ARMSTRONG TEASDALE LLP  
One Metropolitan Square, Suite 2600  
St. Louis, Missouri 63102  
314-621-5070

Via EFS

DEA/ts